

Remarks

This Amendment is in response to the Office Action dated **March 5, 2009**.

Claims 1 and 3 have been amended to delete the word "about." No new matter has been added.

Restriction

The Office Action states that the applicant's previous election is being treated as without traverse. Please note, however, that the applicant has requested rejoinder upon allowance of a generic claim. Rejoinder is provided for under MPEP 821.04 when all elected claims are in condition for allowance and the withdrawn claims depend from an allowable claim, both of which are satisfied here. Applicant therefore again requests that the restricted claims 16-20 be rejoined and allowed.

Claims Rejections 35 USC §103

Claims 1-2, 4-6 and 21-22 have been rejected as obvious from Anderson et al, US 5500180 in view of Euteneuer US 5207700. The rejection is traversed.

Anderson et al, discloses a balloon formed from a polyurethane block copolymer (PELETHANE 2363-75D) that has a flexural modulus of "about 190,000 psi" (189 ksi per current Matweb.com datasheet attached). Claim 1 as currently amended specifies a flexural modulus of 150,000 psi or less, a value less than 80% than that of PELLETHANE 2363-75D. At the time of the invention a skilled person would not have understood that a block copolymer balloon having the properties sought by Anderson et al could be fashioned using a polymer that had a much lower modulus than PELLETHANE 2363-75D. In fact Anderson et al spends a

lot of time discussing the criticality of using a polymer that has the right balance of polymer hard segments and soft segments, see e.g. Col. 8, lines 9-19:

The ratio of hard to soft segments and individual chemical structure of the individual segments define the balloon's distensibility, elastic stress response and strength. Therefore, the polymeric material used in accordance with this invention should have hard segments present in an amount sufficient to achieve a high degree of elastic stress response (i.e., not greater than about 5.00) and adequate wall tensile strength (i.e., at least about 14,000 psi), while at the same time having an adequate amount of soft segments to ensure that the balloon is also distensible (i.e., about 5 to about 20%).

However, Anderson et al provides no way of identifying a polymer that has this right balance. Other than to use the specific PELLETHANE 2363-75D disclosed in Anderson et al, the *only way* that a skilled person can even arguably given to identify a block copolymer that has the right balance of hard and soft segments, is to *match* the physical properties listed in Anderson as characterizing the example material. Anything else is pure trial-and-error from an infinity of options based only on final balloon properties. Furthermore, Anderson et al's teachings as a whole indicate that substantial deviations from the listed properties PELLETHANE 2363-75D cannot be not expected to work. The Anderson balloon uses multiple blow cycles to form (see col. 9, lines 47-51 and Example 1), needs to be heat set after blowing (col. 9, lines 53-63 and Example 1) and "must" be sterilized with a low temperature, low humidity sterilization process (col. 10, lines 38-41 and Example 3), all of which indicate the balloon material choices are *not robust*. All of these facts evidence that a skilled person at the time of the applicant's invention would not have thought that a polymer with a flexural modulus of 150,000 or less, as recited in claim 1, would be a sufficiently close match to 190,000 to provide a reasonable expectation of success based on the Anderson disclosure.

Euteneuer discloses balloons made from polyimides. Polyimides in general are very

high modulus materials and there is no reason to expect that the Euteneuer polyimides are exceptions to this well known general rule. Matweb.com datasheet attached lists flexural modulus for thermoplastic polyimide as 200-4790 ksi, i.e. 200,000 - 4,790,000 psi, at 150-500 °C, (ambient temperature would be expected to be higher). If anything the combination of the two would lead a skilled person to expect that if one can deviate from the flexural modulus of the PELLETHANE 2363-75D, the deviation would be toward *higher* flexural modulus, not lower flexural modulus polymers.

Further with regard to claim 6, the low values of the flexural modulus range specified in this claim (50,000-120,000) are even further from that of Anderson's PELLETHANE 2363-75D (120,000 is less than 65% of 190,000) and from Eutencuer's higher modulus polyimides.

Claims 3 and 7-15 have been rejected as obvious from Anderson et al, US 5500180 in view of Euteneuer US 5207700 as applied to claims 1-2, 4-6 and 21-22, and further in view of Foy et al US 4331786. The rejection is traversed.

Claims 3 and 7-15 depend from claim 1 and so are non-obvious over the combination of Anderson et al, in view of Euteneuer for the reasons given above. Foy et al does not disclose a polymer that on its face is a close match for the properties described for PELLETHANE 2363-75D in Anderson et al. Foy does not suggest that any particular polymer will be suitable as a material for a medical device. Further, the skilled person is not led by Anderson et al, or by the combination of Anderson et al with Euteneuer, to use any particular polymer disclosed in Foy as a medical device balloon material. Note that Foy's references to

balloons appear to be references to toy balloons (see. in particular col. 6, line 65), and so do not suggest suitability for medical device balloons, and in any case if taken as suggesting medical balloons, is not a teaching that a polymer having the physical properties recited in claims 1 or 3 could be so used. At least for this reason the invention is not obvious from Anderson et al, in view of Euteneuer and further in view of Foy et al.

Double Patenting

Claims 1-15 and 21-22 are rejected for obviousness type double patenting over claims 1-17 of US 5,556,383. A terminal disclaimer is enclosed that obviates the grounds for rejection. Withdrawal of the rejection is therefore respectfully requested.

Conclusion

In view of the foregoing amendments and remarks and the enclosed terminal disclaimer the application is in condition for allowance. Withdrawal of the outstanding rejections, withdrawal of the earlier restriction requirement, and allowance of the application are all respectfully requested.

Respectfully submitted,
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encl:

matweb.com datasheets :
PELLETHANE 2363-75D
Overview of Materials for Polyimide.
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